

**SUBSTITUTE SPECIFICATION
CLEAN VERSION**

METHOD OF TREATING SKIN FLAPS AND SKIN GRAFTS WITH SHOCK WAVES

[0001] Summary of the Invention

[0002] The present invention relates to a method for the treatment of soft tissue disorders.

[0003] Since its introduction over 20 years ago ESW therapy has been the method of choice in urolithiasis. The shock waves (pressure waves), which are generated outside the body, can be focused at a specific site within the body. These waves travel through fluid and soft tissue and their effects occur at sites where there is a change in impedance, such as the bone-soft tissue interface. Mainly three mechanisms to generate a focused shock wave are used in medicine: piezoelectric, electromagnetic, and electrohydraulic. All mentioned mechanisms convert electrical energy into a pressure wave within a fluid medium (Gerdesmeyer et al., 2002). To allow the propagation of the waves from the shock wave applicator into the body, a contact medium has to be applied. In clinical practice ultrasonic gel as contact medium is routinely used.

[0004] The common use for shock waves is to break kidney stones into fragments that can then be passed through the urinary passage. It is known that shock waves can also increase cellular permeability, stimulate cellular division and stimulate cytokine production by cells (Wang F S et al., 2000; Kusnierczak et al.; 2000). Recent studies have demonstrated that shock waves induce neovascularization at the tendon-bone junction, which in turn relieves pain and improves tissue regeneration and repairing (Wang C J et al., 2000). Extracorporeal shock wave therapy was also found to have a positive effect on the concentration of transforming growth factor-beta 1, which has a chemotactic and mitogenic effect on osteoblastic cells. There is also some evidence that shock waves may have an effect on nitric oxide synthase systems implicated in bone healing/remodelling (Cavalieri et al., 2002). Shock waves are further routinely used to treat common orthopedic conditions in humans including plantar calcaneal spurs (heel spurs) epicondylopathic humeri radialis (tennis elbow), bone spavin, navicular syndrome, and high suspensory disease among other musculoskeletal diseases. However, at this time, the mechanism or mechanisms that shock waves utilize to stimulate healing in vivo is unknown.

[0005] An important parameter for ESW therapy is the energy level utilized. Microfractures and urolithiasis for example have been seen at high energies. In studies involving the application